Time at Temperature Sterilization Assessment

Prepared by

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State of Louisiana

October 13, 1998

Summary

State of Louisiana
Department of Health and Hospitals
Office of Public Health
Division of Laboratories
*325 Loyola Av. * Suite 709 * New Orleans, LA 70112-1829*

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Time at Temperature Sterilization Assessment

Three separate test runs to determine the lower time at temperature required to reach a 6 Log_{10} and an 8 Log_{10} reduction of microorganisms processed through the Tempico Rotoclave System were performed at the North Oaks Medical Center in Hammond, Louisiana on October 7, 1998. Microbiological assessments of the test organisms were performed the same day at the Amite Public Health Laboratory, Amite, Louisiana.

This document details the assessment procedures, the results of the assessments, interpretation of the results and implications of the results on the lower time required to achieve sterilization.

In general, we have determined that an 8 Log_{10} reduction of the test microorganism is achieved in a 5 minute processing time when all waste is in direct contact with steam at or above 45 psi and 135º C. This would allow Tempico to reduce its current programmed time for the Rotoclave of 30 minutes to 5 minutes and still achieve sterilization.

State of Louisiana
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Office of Public Health
Division of Laboratories
*325 Loyola Av. * Suite 709 * New Orleans, LA 70112-1829*
*Phone-504.568.5371 * 504.568.5393*

Date: October 13, 1998

Subject: Time at Temperature Sterilization Assessment performed October 7, 1998 at North Oaks Medical Center in Hammond Louisiana and Amite Public Health Laboratory

Prepared By: Susan Larsen Daigle
Health Laboratory Assistant Director, Administration
Division of Laboratories, Office of Public Health,
Department of Health and Hospitals

Definition of Terms:
Biological Indicators (BI): A known qualitative and quantitative population of microorganism spores used to determine the efficacy of a sterilization process. There are two BI used in this study. Both are populations of Bacillus stearothermophilus spores. However, the SGM Biotech indicator has an has a 1.0×10^6 population size and the Raven Biological Prospore indicator has a population size of 1.3×10^8.

Rotoclave: Microprocessor controlled steam sterilizers manufactured by Tempico Inc. The instrument has a rotating internal drum that accepts medical waste materials in unopened containers and subjects them to agitation and sterilization at not less than 275 degrees Fahrenheit and not less than 45 psi. The Rotoclave microprocessor automatically records and prints out the parameters of the operation, including the time that the process is held at the required temperature and pressure. The system will not allow the materials to be discharged until all sterilization requirements of time, temperature and pressure have been met. A permanent record of the operation of each processing cycle is automatically printed with the date, time of day, length of processing, temperature, and pressure. After the sterilization parameters of time, temperature and pressure are met, a vacuum/condensing system is engaged to dry the waste. The now sterile, dry waste material is discharged from the Rotoclave through a size reduction system to render all material unrecognizable.

Sterilization: Process of making waste stream free from microorganisms

Spore Ampoule Test Canisters: Stainless steel cylinders used to protect the spore ampoules from breakage during the sterilization cycle. The cylinders are 12 inches in length and 2 inches in diameter with threaded caps to secure contents. Cylinders are perforated every square inch to allow steam penetration.

Waste carts: Ninety-five (95) gallon covered carts that can be wheeled from collection site to Rotoclave for automated loading. Carts are red and marked with biological hazard signs.

Waste stream: Unsorted waste including infectious hospital waste and general, common waste to be processed in the Rotoclave sterilizer. Waste contains an assortment of cardboard containers, linens, surgical gloves, surgical tubing, sharps, specimen cups, plastic bedpans, aluminum cans, foam pads, and red biohazard bags.

Participants:
Representing Louisiana Public Health Division of Laboratories:
Susan Daigle
Richard Samuels

Representing North Oaks Medical Center:
Richie, full time operator

Representing Tempico, Inc.:
Murray Cleveland
Blake Harrison
Clint Jacobs
Terrance Placzek

General Observations:
The sterilized waste had undergone some changes when it was ejected from the Rotoclave following the sterilization process. Aluminum cans were cleaned of identifying labels and markings; rubber gloves were intact; linens were recognizable and somewhat shredded; red biohazard bags and plastic materials were melted and compressed; cardboard and other paper waste were pulverized into small bits.

After the waste passed through the shredder it was collected in BFI waste containers for pick-up and disposal. The final waste product resembled colored confetti. The shape, form, labeling and composition of any original waste product were indistinguishable and unidentifiable. The waste volume was reduced about 60% after the sterilization process. The shredding and grinding process reduced the volume even more resulting in about an 85% overall reduction. The Rotoclave process results in an unrecognizable mass of material that is both pathologically and physically harmless and is disposed of as ordinary, common waste.

Test Run #1

Date:	October 7, 1998
Place:	North Oaks Medical Center
Time:	Approximately 9:30 AM
Test Conditions:	**15 minute** processing time, 45 psi, 135ºC.
Test Instrument:	Rotoclave #2, manufactured by Tempico, Inc.
Biological	1. Prospore Biological Indicator, Raven Biological Lab Inc. Lot Number Indicator Spore Number PS179-1, Batch 257S, expiration date 3/00. Population: Ampoules 1.3 x 10^8 Bacillus stearothermophilus spores, ATCC 7953 2. SGM, Biotech Inc. Lot Number Sc-117, expiration date 10/31/99. Population: 1.0 x 10^6 Bacillus stearothermophilus spores

Procedures
Loading Test Ampoules:

At approximately 9:30 AM, Blake Harrison of Tempico, Inc. loaded the spore ampoules into their protective stainless steel canisters. Mr. Harrison removed three 1.0 x 10^6 ampoules of SGM Biotech B. Stearothermophilus Biological Indicator (BI) and three 1.3 x 10^8.ampoules of Raven Biological Prospore BI from their respective manufacturers carton and placed all six (6) ampoules in the center of a piece of sterile cotton approximately eight inches square. He rolled the cotton securely around the ampoules. He placed an additional piece of cotton in the bottom of the steel canister, added the wrapped ampoules and placed a final piece of sterilized cotton in the top of the stainless steel canister to secure the test ampoules. He tightened the canister cap onto the canister. Blake Harrison repeated the procedure using a second stainless steel canister.

Susan Daigle of the Division of Laboratories (DOL) removed one control ampoule of 1.0 x 10^6 Bacillus stearothermophilus spores and one control ampoule of 1.3 x 10^8 Bacillus stearothermophilus spores from the same manufacturer's carton from which the test ampoules were taken. The ampoules were labeled as positive controls and placed inside a carrier for transport to the Amite PH Laboratory for incubation. Ms. Daigle maintained custody of the controls from this point until transfer to Richard Samuels, Lab Scientist Manager of the Amite PH Lab for incubation.

Rotoclave Sterilization Cycle:
A total of five (5) 95 gallon waste carts of mixed waste were automatically loaded into Rotoclave #2 for the test. Terrence Placzek estimated the weight of each container to be

about 50 lbs., resulting in a total load of about 250 lbs. Clint Jacobs of Tempico and Richie of North Oaks, placed four waste carts of mixed waste on the Rotoclave #2 automated loader. Murray Cleveland of Tempico loaded 2 spore ampoule canisters into the sterilizer and the fifth waste cart was then loaded. The door was closed at approximately 9:40 AM and the sterilization cycle started. Richie and Clint Jacobs jointly operated and monitored the sterilization cycle from the Rotoclave microprocessor panel and printouts.

As the sterilization cycle proceeded, the Rotoclave reached its operating temperature and pressure in about 12 minutes and proceeded uninterrupted to completion. The door was then opened at about 10:10 AM. The sterilizer automatically emptied its contents onto a conveyor belt for transport to the shredders. Both ampoule canisters were recovered as they tumbled onto the conveyor belt and were placed aside to cool for 10 minutes. The waste proceeded up the conveyor, toward the shredders.

Spore Ampoule Recovery
The spore ampoules were allowed to cool for about 10 minutes. Blake Harrison and Murray Cleveland of Tempico removed the cotton wrapped ampoules from their protective canisters. The cotton was unwrapped, and six ampoules were recovered unbroken from the canister. Susan Daigle of LA Public Health Laboratories took possession of the ampoules and placed them in a labeled container for transport to the Amite PH Laboratory for incubation. The procedure was repeated to remove the ampoules from the second canister. Custody of these ampoules was maintained by Blake Harrison for delivery to Central Analytical Laboratories in Belle Chasse Louisiana for incubation.

Spore Ampoule Incubation
Ms. Daigle transported the set of six ampoules/set to the Amite PH Laboratory at 104-A 1st Street, Amite, Louisiana. Each ampoule was given a unique lab number and individually labeled with pertinent process information including the TAT test #, the sterilization run time, the spore population size, the date and time of incubation. Richard Samuels, Laboratory Scientist Manager of the Amite Lab crushed the internal media reservoir, providing access to a nutrient source for any viable organisms.

The two unprocessed control ampoules (1.0×10^6 and 1.3×10^8 Bacillus stearothermophilus spores) were activated in the same manner. The test samples and the control samples were placed in a rack and put into an incubator for a period of five days. The incubation start time was October 7, 1998 at 1:30 PM and time out of incubation was October 12, 1998 at 8:00 AM. The Incubator Temperature was recorded at 56ºC and was monitored twice daily during the incubation period. The temperature remained stable at 56ºC throughout the incubation period.

Richard Samuels examined the indicators at regular intervals (i.e., 24 hours, 48 hours, 96 hours and 5 days) for any color change. According to the manufacturer, the appearance of a yellow color read-out indicates bacteria growth. This is a function of the pH indicator

that responds to a pH change due to the growth of the organisms. No color change from the initial color indicates adequate sterilization. At the end of the incubation period, Mr. Samuels removed the spore ampoules from the incubator. He did a final examination for signs of growth and recorded the results. The following is a tabulation of observations:

Assessment Report

Test #	TAT	Spore Population	Location	Sample Number	BI Color	BI Result
QA	0	1.0×10^6	Positive Control	TATQA6	Yellow	Growth
QA	0	1.3×10^8	Positive Control	TATQA8	Yellow	Growth
1	15 min	1.0×10^6	Rotoclave #2	TAT1007981	Red	Sterile
1	15 min	1.0×10^6	Rotoclave #2	TAT1007982	Red	Sterile
1	15 min	1.0×10^6	Rotoclave #2	TAT1007983	Not Tested	Not Tested
1	15 min	1.3×10^8	Rotoclave #2	TAT1007984	Purple	Sterile
1	15 min	1.3×10^8	Rotoclave #2	TAT1007985	Purple	Sterile
1	15 min	1.3×10^8	Rotoclave #2	TAT1007986	Purple	Sterile

There was no media in sample # TAT1007983 when it was examined for labeling, prior to incubation. The sample was considered unsatisfactory for assessment and was discarded. It is not known if the sample leaked during process or was empty when it was removed from the manufacturer's carton and placed in the canister. The other two spore ampoules with a 1.0×10^6 B. stearothermophilus spore population did not change color following incubation. This indicates that the sterilization cycles was effective in killing the B. stearothermophilus spores, when normal operating conditions of 135ºC and 45 psi were maintained for a period of 15 minutes.

The unsterilized 1.0×10^6 BI control showed a color change to yellow, indicating a pH change due to growth of the B. stearothermophilus spores. This data indicates that the Biological Indicators are viable.

The test spore ampoules from Rotoclave #2 with a 1.3×10^8 B. stearothermophilus spore population remained purple following incubation. This indicates that the sterilization cycles was effective in killing the B. stearothermophilus spores, when normal operating conditions of 135ºC and 45 psi were maintained for a period of 15 minutes.

The unsterilized 1.3×10^8 BI control showed a color change to yellow, indicating a pH change due to growth of the B. stearothermophilus spores. This data indicates that the Biological Indicators are viable.

Interpretation
Sterilization was achieved to a level of 8 Log 10 when the time at sterilization temperature and pressure of Rotoclave #2 were held for 15 minutes.

Impact:
The Rotoclave exceeds the regulatory 6 log 10 reduction of microorganisms and is capable of achieving an 8 Log 10 reduction of B. stearothermophilus spores with a programmed processing time of 15 minutes during which there is direct contact of the steam with all waste at or above 45 psi and 135ºC.

Test Run #2

Date:	October 7, 1998
Place:	North Oaks Medical Center
Time:	Approximately 9:50 AM

Test Conditions: 10 (ten) minute processing time, 45 psi, 135ºC.

Test Instrument: Rotoclave #1, manufactured by Tempico, Inc.

Biological Indicator Spore Ampoules	1. Prospore Biological Indicator, Raven Biological Lab Inc. Lot Number PS179-1, Batch 257S, expiration date 3/00. Population: 1.3×10^8 Bacillus stearothermophilus spores, ATCC 7953
	2. SGM, Biotech Inc. Lot Number Sc-117, expiration date 10/31/99. Population: 1.0×10^6 Bacillus stearothermophilus spores

Procedures

Loading Test Ampoules:
At Approximately 9:50 AM, Blake Harrison of Tempico, Inc. loaded the spore ampoules into their protective stainless steel canisters. Mr. Harrison removed three 1.0×10^6 ampoules of SGM Biotech B. stearothermophilus Biological Indicator (BI) and three 1.3×10^8 ampoules of Raven Biological Prospore BI from their respective manufacturers carton and placed all six (6) ampoules in the center of a piece of sterile cotton approximately eight inches square. He rolled the cotton securely around the ampoules. He placed an additional piece of cotton in the bottom of the steel canister, added the wrapped ampoules and placed a final piece of sterilized cotton in the top of the stainless steel canister to secure the test ampoules. He tightened the canister cap onto the canister. Blake Harrison repeated the procedure using a second stainless steel canister.

Rotoclave Sterilization Cycle:
A total of four (4) 95 gallon waste carts of mixed waste were automatically loaded into Rotoclave #1 for the test, resulting in a total load of about 200 lbs. Clint Jacobs of Tempico and Richie of North Oaks, placed two waste carts of mixed waste on the Rotoclave #1 automated loader. Murray Cleveland of Tempico loaded 2 spore ampoule canisters into the sterilizer after which two additional waste carts were loaded. The door was then closed at approximately 10:00 AM and the sterilization cycle started. Richie and Clint Jacobs jointly operated and monitored the sterilization cycle from the Rotoclave microprocessor panel and print-outs.

As the sterilization cycle proceeded, the Rotoclave reached its operating temperature and pressure in about 12 minutes and proceeded uninterrupted to completion. The door was opened at about 10:30 AM. The sterilizer automatically emptied its contents onto a conveyor belt for transport to the shredders. Both ampoule canisters were recovered as they tumbled onto the conveyor belt and were placed aside to cool for 10 minutes. The waste proceeded up the conveyor, toward the shredders.

Spore Ampoule Recovery
The spore ampoules were allowed to cool for about 10 minutes. Blake Harrison and Murray Cleveland of Tempico removed the cotton wrapped ampoules from their protective canisters. The cotton was unwrapped, and six ampoules were recovered unbroken from the canister. Susan Daigle of LA Public Health Laboratories took possession of the ampoules and placed them in a labeled container for transport to the Amite PH Laboratory for incubation. The procedure was repeated to remove the ampoules from the second canister. Custody of these ampoules was maintained by Blake Harrison for delivery to Central Analytical Laboratories in Belle Chasse Louisiana for incubation.

Spore Ampoule Incubation
Ms. Daigle transported the set of six ampoules/set to the Amite PH Laboratory at 104-A 1st Street, Amite Louisiana. Each ampoule was given a unique lab number and individually label with pertinent process information including the TAT test #, the sterilization run time, the spore population size, the date, and time of incubation. Richard Samuels, Laboratory Scientist Manager of the Amite Lab crushed the internal media reservoir, providing access to a nutrient source for any viable organisms.

The two unprocessed control ampoules (1.0×10^6 and 1.3×10^8 Bacillus stearothermophilus spores) were activated in the same manner. The test samples and the control samples were placed in a rack and put into an incubator for a period of 5 days. The incubation start time was October 7, 1998 at 1:30 PM and time out of incubation was October 12, 1998 at 8:00 AM. The Incubator Temperature was recorded at 56ºC and was monitored twice daily during the incubation period. The temperature remained stable at 56ºC throughout the incubation period.

Richard Samuels examined the indicators at regular intervals (i.e., 24 hours, 48 hours, 96 hours and 5 days) for any color change. According to the manufacturer, the appearance of a yellow color read-out indicates bacteria growth. This is a function of the pH indicator that responds to a pH change due to the growth of the organisms. No color change from the initial color indicates adequate sterilization. At the end of the incubation period, Mr. Samuels removed the spore ampoules from the incubator. He did a final examination for signs of growth and recorded the results. The following is a tabulation of observations:

Assessment Report

Test #	TAT	Spore Population	Location	Sample Number	BI Color	BI Result
QA	0	1.0×10^6	Positive Control	TATQA6	Yellow	Growth
QA	0	1.3×10^8	Positive Control	TATQA8	Yellow	Growth
2	10 min	1.0×10^6	Rotoclave #1	TAT1007987	Red	Sterile
2	10 min	1.0×10^6	Rotoclave #1	TAT1007988	Red	Sterile
2	10 min	1.0×10^6	Rotoclave #1	TAT1007989	Red	Sterile
2	10 min	1.3×10^8	Rotoclave #1	TAT10079810	Purple	Sterile
2	10 min	1.3×10^8	Rotoclave #1	TAT10079811	Purple	Sterile
2	10 min	1.3×10^8	Rotoclave #1	TAT10079812	Purple	Sterile

The test spore ampoules with a 1.0×10^6 B. stearothermophilus spore population did not change color following incubation. This indicates that the sterilization cycle was effective in killing the B. stearothermophilus spores when normal operating conditions of 135ºC and 45 psi were maintained for a period of 10 minutes.

The unsterilized 1.0×10^6 BI control showed a color change to yellow, indicating a pH change due to growth of the B. stearothermophilus spores. This data indicates that the Biological Indicators are viable.

The test spore ampoules from Rotoclave #1 with a 1.3×10^8 B. stearothermophilus spore population did not change color following incubation. This indicates that the sterilization cycle was effective in killing the B. stearothermophilus spores when normal operating conditions of 135ºC and 45 psi were maintained for a period of 10 minutes.

The unsterilized 1.3×10^8 BI control showed a color change to yellow, indicating a pH change due to growth of the B. stearothermophilus spores. This data indicates that the Biological Indicators are viable.

Interpretation
Sterilization was achieved when the time at sterilization temperature and pressure of Rotoclave #1 were held for 10 (ten) minutes.

Impact:
The Rotoclave exceeds the regulatory 6 log 10 reduction of microorganisms and is capable of achieving an 8 Log reduction of B. stearothermophilus spores with a programmed processing time of 10 minutes during which there is direct contact of the steam with all waste at or above 45 psi. and 135ºC.

Test Run #3

Date:	October 7, 1998
Place:	North Oaks Medical Center
Time:	Approximately 10:50 AM

Test Conditions: **5 (five) minute** processing time, 45psi, 135ºC.

Test Instrument: Rotoclave #2, manufactured by Tempico Inc.

Biological Indicator Spore Ampoules	1. Prospore Biological Indicator, Raven Biological Lab Inc. Lot Number PS179-1, Batch 257S, expiration date 3/00. Population: 1.3×10^8 Bacillus stearothermophilus spores, ATCC 7953 2. SGM, Biotech Inc. Lot Number Sc-117, expiration date 10/31/99. Population: 1.0×10^6 Bacillus stearothermophilus spores

Procedures

Loading Test Ampoules:
At approximately 10:40 AM, Blake Harrison of Tempico, Inc. loaded the spore ampoules into their protective stainless steel canisters. Mr. Harrison removed three 1.0×10^6 ampoules of SGM Biotech B. stearothermophilus Biological Indicator (BI) and three 1.3×10^8 ampoules of Raven Biological Prospore BI from their respective manufacturers carton and placed all six (6) ampoules in the center of a piece of sterile cotton approximately eight inches square. He rolled the cotton securely around the ampoules. He placed an additional piece of cotton in the bottom of the steel canister, added the wrapped ampoules and placed a final piece of sterilized cotton in the top of the stainless steel canister to secure the test ampoules. He tightened the canister cap onto the canister. Blake Harrison repeated the procedure using a second stainless steel canister.

Rotoclave Sterilization Cycle:
A total of five (5) 95 gallon waste carts of mixed waste were automatically loaded into Rotoclave #2 for the test, resulting in a total load of about 250 lbs. Clint Jacobs of Tempico and Richie of North Oaks, placed three waste carts of mixed waste on the Rotoclave #2 automated loader. Murray Cleveland of Tempico loaded 2 spore ampoule canisters into the sterilizer after which two additional waste carts were loaded. The door was then closed at approximately 10:50 AM and the sterilization cycle started. Richie and Clint Jacobs jointly operated and monitored the sterilization cycle from the Rotoclave microprocessor panel and print-outs.

As the sterilization cycle proceeded, the Rotoclave reached its operating temperature and pressure in about 12 minutes and proceeded to the vacuum reduction stage. At this point a vapor valve stuck. Terrence Placzek and Clint Jacobs from Tempico rerouted the pressure release through a smaller outlet and the cycle continued to completion at a slower pace than the previous cycles. It required about 20 additional minutes for completion. However, the process had progressed to the final phase at the time of the stuck valve so there was no impact on the sterilization process itself. The door was then opened at about 11:40AM. The sterilizer automatically emptied its contents onto a conveyor belt for transport to the shredders. Both ampoule canisters were recovered as they tumbled onto the conveyor belt and were placed aside to cool for 10 minutes. The waste proceeded up the conveyor, toward the shredders.

Spore Ampoule Recovery
The spore ampoules were allowed to cool for about 10 minutes. Blake Harrison and Murray Cleveland of Tempico removed the cotton wrapped ampoules from their protective canisters. The cotton was unwrapped, and six ampoules were recovered unbroken from the canister. Susan Daigle of LA Public Health Laboratories took possession of the ampoules and placed them in a labeled container for transport to the Amite PH Laboratory for incubation. The procedure was repeated to remove the ampoules from the second canister. Custody of these ampoules were maintained by Blake Harrison for delivery to Central Analytical Laboratories in Belle Chasse Louisiana for incubation.

Spore Ampoule Incubation
Ms. Daigle transported the set of six ampoules/set to the Amite PH Laboratory at 104-A 1st Street, Amite Louisiana. Each ampoule was given a unique lab number and individually label with pertinent process information including the TAT test #, the sterilization run time, the spore population size, the date and time of incubation. Richard Samuels, Laboratory Scientist Manager of the Amite Lab crushed the internal media reservoir, providing access to a nutrient source for any viable organisms.

The two unprocessed control ampoules (1.0×10^6 and 1.3×10^8 Bacillus stearothermophilus spores) were activated in the same manner. The test samples and the control samples were placed in a rack and put into an incubator for a period of 5 days. The incubation start time was October 7, 1998 at 1:30 PM and time out of incubation was October 12, 1998 at 8:00 AM. The Incubator Temperature was recorded at 56°C and was monitored twice daily during the incubation period. The temperature remained stable at 56°C throughout the incubation period.

Richard Samuels examined the indicators at regular intervals (i.e., 24 hours, 48 hours, 96 hours, and 5 days) for any color change. According to the manufacturer, the appearance of a yellow color read-out indicates bacteria growth. This is a function of the pH indicator that responds to a pH change due to the growth of the organisms. No color change from the initial color indicates adequate sterilization. at the end of the incubation period, Mr. Samuels removed the spore ampoules from the incubator. He did a final

examination for signs of growth and recorded the results. The following is a tabulation of observations:

Assessment Report

Test #	TAT	Spore Population	Location	Sample Number	BI Color	BI Result
QA	0	1.0×10^6	Positive Control	TATQA6	Yellow	Growth
QA	0	1.3×10^8	Positive Control	TATQA8	Yellow	Growth
3	5 min	1.0×10^6	Rotoclave #2	TAT10079813	Red	Sterile
3	5 min	1.0×10^6	Rotoclave #2	TAT10079814	Red	Sterile
3	5 min	1.0×10^6	Rotoclave #2	TAT10079815	Red	Sterile
3	5 min	1.3×10^8	Rotoclave #2	TAT10079816	Purple	Sterile
3	5 min	1.3×10^8	Rotoclave #2	TAT10079817	Purple	Sterile
3	5 min	1.3×10^8	Rotoclave #2	TAT10079818	Purple	Sterile

The test spore ampoules with a 1.0×10^6 B. stearothermophilus spore population did not change color following incubation. This indicates that the sterilization cycle was effective in killing the B. stearothermophilus spores when normal operating conditions of 135°C and 45 psi were maintained for a period of 10 minutes.

The unsterilized 1.0×10^6 BI control showed a color change to yellow, indicating a pH change due to growth of the B. stearothermophilus spores. This data indicates that the Biological Indicators are viable.

The test spore ampoules from Rotoclave #1 with a 1.3×10^8 B. stearothermophilus spore population did not change color following incubation. This indicates that the sterilization cycle was effective in killing the B. stearothermophilus spores when normal operating conditions of 135°C and 45 psi were maintained for a period of 10 minutes.

The unsterilized 1.3×10^8 BI control showed a color change to yellow, indicating a pH change due to growth of the B. stearothermophilus spores. This data indicates that the Biological Indicators are viable.

Interpretation
Sterilization was achieved when the time at sterilization temperature and pressure of Rotoclave #1 were held for 5 (five) minutes.

Impact:
The Rotoclave exceeds the regulatory 6 log 10 reduction of microorganisms and is capable of achieving an 8 Log reduction of B. stearothermophilus spores with a programmed processing time of only five minutes during which there is direct contact of the steam with all waste at or above 45 psi and 135°C.

Summary Tables

Division Of Laboratories
325 Loyola Ave ò Suite 709 ò New Orleans La 70112-1829
Phone- 504.568.5371 * FAX - 504.568.5393

TO: Murray F. Cleveland. Jr.
Tempico Medical Processing Company, Inc.
251 Hwy. 21 North P.O. Box 428 Madisonville, LA 70447

Assessment Report for Test Run # 1

Test Site: Amite Regional Public Health Laboratory
Date Received: October 7,1998
Date Reported: October 12, 1998 Reported By: Susan Daigle

Lab Number	Description	Results	Interpretation
TAT1007981 TAT1007982	Processed Bacillus stearothermophilus spore ampoule. Manufacturer: SGM, Biotech Inc. Lot Number Sc-117, expiration date 10/31/99. Population: 1.0 x 10^6 Bacillus stearothermophilus spores. Processed in Rotoclave # 2	All 3 of the test spore ampoules with a 1.0 x 10^6 B. stearothermophilus spore population remained red following incubation.	This indicates that the sterilization cycle was effective in killing the B. stearothermophilus spores, when normal Rotoclave # 2 operating conditions were maintained for a period of 15 (fifteen) minutes.
TAT1007984 TAT1007985 TAT1007986	Processed Bacillus stearothermophilus spore ampoule. Manufacturer: Prospore Biological Indicator, Raven Biological Lab Inc. Lot Number PS179-1, Batch 257S, and expiration date 3/00. Population: 1.3 x 10^8 Bacillus stearothermophilus spores, ATCC 7953. Processed in Rotoclave # 2.	All 3 of the test spore ampoules with a 1.3 x 10^8 B. stearothermophilus spore population remained purple following incubation.	This indicates that the sterilization cycle was effective in killing the B. stearothermophilus spores, when normal Rotoclave # 2 operating conditions were maintained for a period of 15 (fifteen) minutes.
TAT1007983	There was no media in the ampoule when it was examined for labeling, prior to incubation.	Not tested	No results

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Lab Number	Description	Results	Interpretation
TATQA6	Unprocessed Bacillus stearothermophilus spore ampoule. Manufacturer: SGM, Biotech Inc. Lot Number Sc-117, expiration date 10/31/99. Population: 1.0×10^6 Bacillus stearothermophilus spores.	The unprocessed BI control showed a color change from red to yellow, indicating a pH change due to growth of the B. stearothermophilus spores.	This data indicates that the Biological Indicators are viable.
TATQA8	Unprocessed Bacillus stearothermophilus spore ampoule. Manufacturer: Prospore Biological Indicator, Raven Biological Lab Inc. Lot Number PS179-1, Batch 257S, and expiration date 3/00. Population: 1.3×10^8 Bacillus stearothermophilus spores, ATCC 7953.	The unprocessed BI control showed a color change from purple to yellow, indicating a pH change due to growth of the B. stearothermophilus spores.	This data indicates that the Biological Indicators are viable.

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TO: Murray F. Cleveland. Jr.
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Assessment Report for Test Run # 2

Test Site: Amite Regional Public Health Laboratory
Date Received: October 7,1998
Date Reported: October 12, 1998 Reported By: Susan Daigle

Lab Number	Description	Results	Interpretation
TAT1007987 TAT1007988 TAT1007989	Processed Bacillus stearothermophilus spore ampoule. Manufacturer: SGM, Biotech Inc. Lot Number Sc-117, expiration date 10/31/99. Population: 1.0 x 10^6 Bacillus stearothermophilus spores. Processed in Rotoclave #1	All 3 of the test spore ampoules with a 1.0 x 10^6 B. stearothermophilus spore population remained red following incubation.	This indicates that the sterilization cycle was effective in killing the B. stearothermophilus spores, when normal Rotoclave # 1 operating conditions were maintained for a period of 10 (ten) minutes.
TAT10079810 TAT10079811 TAT10079812	Processed Bacillus stearothermophilus spore ampoule. Manufacturer: Prospore Biological Indicator, Raven Biological Lab Inc. Lot Number PS179-1, Batch 257S, and expiration date 3/00. Population: 1.3 x 10^8 Bacillus stearothermophilus spores, ATCC 7953. Processed in Rotoclave # 1	All 3 of the test spore ampoules with a 1.3 x 10^8 B. stearothermophilus spore population remained purple following incubation.	This indicates that the sterilization cycle was effective in killing the B. stearothermophilus spores, when normal Rotoclave # 1 operating conditions were maintained for a period of 10 (ten) minutes.

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Lab Number	Description	Results	Interpretation
TATQA6	Unprocessed Bacillus stearothermophilus spore ampoule. Manufacturer: SGM, Biotech Inc. Lot Number Sc-117, expiration date 10/31/99. Population: 1.0 x 10^6 Bacillus stearothermophilus spores.	The unprocessed BI control showed a color change from red to yellow, indicating a pH change due to growth of the B. stearothermophilus spores.	This data indicates that the Biological Indicators are viable.
TATQA8	Unprocessed Bacillus stearothermophilus spore ampoule. Manufacturer: Prospore Biological Indicator, Raven Biological Lab Inc. Lot Number PS179-1, Batch 257S, and expiration date 3/00. Population: 1.3 x 10^8 Bacillus stearothermophilus spores, ATCC 7953.	The unprocessed BI control showed a color change from purple to yellow, indicating a pH change due to growth of the B. stearothermophilus spores.	This data indicates that the Biological Indicators are viable.

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TO: Murray F. Cleveland. Jr.
Tempico Medical Processing Company, Inc.
251 Hwy. 21 North P.O. Box 428 Madisonville, LA 70447

Assessment Report for Test Run # 3

Test Site: Amite Regional Public Health Laboratory
Date Received: October 7,1998
Date Reported: October 12, 1998 Reported By: Susan Daigle

Lab Number	Description	Results	Interpretation
TAT10079813 TAT10079814 TAT10079815	Processed Bacillus stearothermophilus spore ampoule. Manufacturer: SGM, Biotech Inc. Lot Number Sc-117, expiration date 10/31/99. Population: 1.0 x 10^6 Bacillus stearothermophilus spores. Processed in Rotoclave # 2.	All 3 of the test spore ampoules with a 1.0 x 10^6 B. stearothermophilus spore population remained red following incubation.	This indicates that the sterilization cycle was effective in killing the B. stearothermophilus spores, when normal Rotoclave # 2 operating conditions were maintained for a period of 5 (five) minutes.
TAT10079816 TAT10079817 TAT10079818	Processed Bacillus stearothermophilus spore ampoule. Manufacturer: Prospore Biological Indicator, Raven Biological Lab Inc. Lot Number PS179-1, Batch 257S, and expiration date 3/00. Population: 1.3 x 10^8 Bacillus stearothermophilus spores, ATCC 7953. Processed in Rotoclave # 2.	All 3 of the test spore ampoules with a 1.3 x 10^8 B. stearothermophilus spore population remained purple following incubation.	This indicates that the sterilization cycle was effective in killing the B. stearothermophilus spores, when normal Rotoclave # 2 operating conditions were maintained for a period of 5 (five) minutes.

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Summary Report

Test Site: Amite Regional Public Health Laboratory
Date Received: October 7,1998
Date Reported: October 12, 1998 Reported By: Susan Daigle

Test #	TAT	Spore Population	Location	Sample Number	BI Color	BI Result
QA	0	1.0×10^6	Positive Control	TATQA6	Yellow	Growth
QA	0	1.3×10^8	Positive Control	TATQA8	Yellow	Growth
1	15 min	1.0×10^6	Rotoclave #2	TAT1007981	Red	Sterile
1	15 min	1.0×10^6	Rotoclave #2	TAT1007982	Red	Sterile
1	15 min	1.0×10^6	Rotoclave #2	TAT1007983	Not Tested	Not Tested
1	15 min	1.3×10^8	Rotoclave #2	TAT1007984	Purple	Sterile
1	15 min	1.3×10^8	Rotoclave #2	TAT1007985	Purple	Sterile
1	15 min	1.3×10^8	Rotoclave #2	TAT1007986	Purple	Sterile
2	10 min	1.0×10^6	Rotoclave # 1	TAT1007987	Red	Sterile
2	10 min	1.0×10^6	Rotoclave # 1	TAT1007988	Red	Sterile
2	10 min	1.0×10^6	Rotoclave # 1	TAT1007989	Red	Sterile
2	10 min	1.3×10^8	Rotoclave # 1	TAT10079810	Purple	Sterile
2	10 min	1.3×10^8	Rotoclave # 1	TAT10079811	Purple	Sterile
2	10 min	1.3×10^8	Rotoclave # 1	TAT10079812	Purple	Sterile
3	5 min	1.0×10^6	Rotoclave #2	TAT10079813	Red	Sterile
3	5 min	1.0×10^6	Rotoclave #2	TAT10079814	Red	Sterile
3	5 min	1.0×10^6	Rotoclave #2	TAT10079815	Red	Sterile
3	5 min	1.3×10^8	Rotoclave #2	TAT10079816	Purple	Sterile
3	5 min	1.3×10^8	Rotoclave #2	TAT10079817	Purple	Sterile
3	5 min	1.3×10^8	Rotoclave #2	TAT10079818	Purple	Sterile